

1 I claim:

✓ 1. A method of treating a disease that results from a deficiency of a biological factor in a mammal wherein said method comprises administering Sertoli cells and a therapeutically effective amount of cells that produce said biological factor to a mammal in need of such treatment, wherein said Sertoli cells are administered in an amount effective to create an immunologically privileged site.

10 2. The method of Claim 1 wherein said mammal is a human.

3. The method of Claim 1 wherein said biological factor is a hormone.

15 4. The method of Claim 1 wherein said biological factor is insulin and said disease is diabetes mellitus.

5. The method of Claim 4 wherein said cells that produce said biological factor are pancreatic islet of Langerhans cells.

20 6. The method of Claim 1 wherein said cells that produce said biological factor are cells transformed by a nucleic acid encoding said biological factor.

25 7. The method of Claim 1 wherein said administering is by transplantation.

8. The method of Claim 1 wherein said Sertoli cells are administered in a dosage ranging from 10^5 to 10^{10} cells.

30 9. The method of Claim 1 wherein said cells that produce said biological factor are administered in a dosage of from 10^5 to 10^{10} cells.

35

08747422-110896

1 10. The method of Claim 7 wherein said
transplantation is by xenograft.

 11. The method of Claim 7 wherein said
transplantation is by allograft.

5 12. The method of Claim 1 which further
comprises administering an immunosuppressive agent.

 13. The method of Claim 12 wherein said
immunosuppressive agent is administered for a time
sufficient to permit said transplanted cells to be
10 functional.

 14. The method of Claim 12 wherein said
immunosuppressive agent is cyclosporine.

 15. The method of Claim 14 wherein said
cyclosporine is administered at a dosage of from 5 to 40
15 mg/kg body wt.

 16. The method of Claim 1 which further
comprises administering a therapeutically effective
amount of exogenous biological factor following the
transplantation of said cells that produce said
20 biological factor.

 17. The method of Claim 1 wherein said cells
that produce said biological factor are co-cultured with
Sertoli cells in tissue culture.

 18. The method of Claim 17 wherein said cells
that produce said biological factor are cryopreserved
25 prior to co-culturing with Sertoli cells in tissue
culture.

 19. A method of treating diabetes mellitus in
a mammal wherein said method comprises administering to
30 a diabetic mammal Sertoli cells in an amount effective
to create an immunologically privileged site and a

1 therapeutically effective amount of pancreatic islet of Langerhans cells.

20. The method of Claim 19 wherein said diabetes mellitus is type I or type II.

5 21. The method of Claim 19 wherein said mammal is a human.

22. The method of Claim 19 wherein said Sertoli cells are human, bovine or porcine.

10 23. The method of Claim 19 wherein said pancreatic islet of Langerhans cells are human, bovine or porcine.

24. The method of Claim 19 wherein said administering is by transplantation.

15 25. The method of Claim 24 wherein said transplantation is by injection into the renal subcapsular space.

26. The method of Claim 24 wherein said transplantation is by injection into the subcutaneous facie.

20 27. The method of Claim 19 wherein said Sertoli cells are administered at a dosage ranging from 10^5 to 10^{10} cells.

25 28. The method of Claim 19 wherein said islet of Langerhans cells are administered at a dosage ranging from 5-1000 islet cells/g body wt.

29. The method of Claim 19 which further comprises the administration of an immunosuppressive agent.

30 30. The method of Claim 29 wherein said immunosuppressive agent is administered for a time sufficient to permit the transplanted islets to be functional.

1 31. The method of Claim 29 wherein said
immunosuppressive agent is cyclosporine.

5 32. The method of Claim 31 wherein said
cyclosporine is administered at a dosage of 5 to 40
mg/kg body wt.

 33. The method of Claim 19 which further
comprises administering a therapeutically effective
amount of insulin following transplantation of said
pancreatic islet of Langerhans cells.

10 ✓ 34. A method of creating an immunologically
privileged site in a mammal wherein said method
comprises transplanting isolated Sertoli cells into a
mammal.

15 35. The method of Claim 34 wherein said mammal
is a human.

 36. The method of Claim 34 wherein said
Sertoli cells are injected into the renal subcapsular
space.

20 37. The method of Claim 34 wherein said
Sertoli cells are injected into the subcutaneous facie.

 38. The method of Claim 34 wherein said
Sertoli cells are transplanted at a dosage ranging from
10⁵ to 10¹⁰ cells.

25 39. The method of Claim 34 wherein said
Sertoli cells are human, bovine or porcine.

30 ✓ 40. A method of enhancing the recovery and
proliferation of ex vivo cells comprising co-culturing
said cells with Sertoli cells for a time and under
conditions sufficient to achieve said enhanced recovery
and proliferation.

1 ✓ 41. A pharmaceutical composition comprising 101
Sertoli cells and cells that produce a biological factor
and a pharmaceutically acceptable carrier.

5 42. The composition of Claim 41 wherein said
biological factor is a hormone.

43. The composition of Claim 41 wherein said
cells that produce a biological factor are pancreatic
islet of Langerhans cells.

10 44. The composition of Claim 41 wherein said
cells that produce said biological factor are cells that
are transformed by a nucleic acid encoding said
biological factor.

15 ✓ 45. A pharmaceutical composition comprising
Sertoli cells, pancreatic islet of Langerhans cells and
a pharmaceutically acceptable carrier.

✓ 46. A pharmaceutical composition comprising
Sertoli cells and a pharmaceutically acceptable carrier.

20 ✓ 47. A compartmentalized kit adapted to receive
a first container adapted to contain Sertoli cells and a
second container adapted to contain cells that produce a
biological factor that is absent or defective in a
disease.

25 ✓ 48. A compartmentalized kit adapted to receive
a first container adapted to contain Sertoli cells and a
second container adapted to contain pancreatic islet of
Langerhans cells.

30 ✓ 49. An article of manufacture comprising a
packaging material and Sertoli cells contained within
said packaging material, wherein said Sertoli cells are
effective for creating an immunologically privileged
site in a mammal, and wherein said packaging material
contains a label that indicates that said Sertoli cells

534
NOV-03V
MM-SM
1534

1 can be used for creating an immunologically privileged
site in a mammal.

5

10

15

20

25

30

35

08747122-110896
968077-2274280

add
B1